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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/065,330 | 04/23/1998 | AMEAE M. WALKER | 2500.097US2 | 7326 |

20995 7590 08/25/2003

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EXAMINER

SAOUD, CHRISTINE J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 08/25/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/065,330

Applicant(s)
WALKER

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 2, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11 is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 June 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments and Declaration filed 02 June 2003 have been fully considered. Claims 1-6 and 9-11 are pending in the instant application.
5. The Declaration under 37 CFR 1.132 filed 02 June 2003 is sufficient to overcome the rejection of claims 1-6 and 9-11 based upon obviousness over the combination of Cooke et al. (U.S. Pat. No. 4,725,549) and A. M. Walker (TEM, 5(5): 195-200) in view of Maciejewski et al. (J. Biol. Chem. 270(17): 27661-27665, 1995).

The Declaration is persuasive in the fact that the bovine S90 mutant is a weak antagonist, while the human S179 mutant is a super-antagonist. Even if the prior art would make obvious the invention as claimed for the substitution of position 179, the result of the substitution is an unexpected result in that the mutant obtained is a much greater antagonist than would have been predicted from the same type of substitution in the bovine protein. (*Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901). However, the unexpected results must be reasonably commensurate in scope with what is being claimed (see *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983)).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a human prolactin mutant wherein the serine at position 179 is substituted with aspartate or glutamate, does not reasonably provide enablement for "species equivalents" or other mutations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims encompass nucleic acid molecules which encode mutated prolactin of SEQ ID NO:1 "or a species equivalent", wherein the encoded protein mimics phosphorylated prolactin "corresponding to a selected species", wherein the mimic antagonizes non-phosphorylated prolactin and encompasses any mutation corresponding to the serine at position 179. The instant specification discloses mutation of human prolactin at position 179, by substitution with aspartate or glutamate for the native serine. The substituted protein has the activity of being a super-antagonist to non-phosphorylated human prolactin. As pointed out above, this result is unexpected in light of the prior art of record. However, the instant specification fails to teach any other mutations (other amino acids or other types of mutations) which would be expected to result in an antagonistic molecule compared to non-phosphorylated prolactin, as well as failing to teach substitution in any other species of prolactin. As pointed out in the Declaration of paper #38, the human substituted protein is unexpectedly a super-antagonist compared to the bovine substituted protein. The record does not establish that this result could be expected of mutation of other species of prolactin because substitution of the major phosphorylation site in the bovine protein did not produce this result. It would be obvious to try the substitution with other species, but this is merely an invitation to experiment. It is noted that the instant specification contemplates substitution of rat prolactin (position 177 corresponds to the human 179), but there is no data with which to compare to determine if the unexpected results carries over to the corresponding position in other species. It is not scientifically prudent to attempt to extrapolate unexpected results from a single data point to a genus of compounds, therefore, the breadth of the claims is not commensurate in scope with the instant disclosure and

unexpected results presented in the Declaration. It would require undue experimentation to practice the claimed invention because one of ordinary skill in the art would not have a reasonable expectation of success in mutating other species of prolactin and producing an antagonistic molecule.

Conclusion

8. Claims 9-11 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud